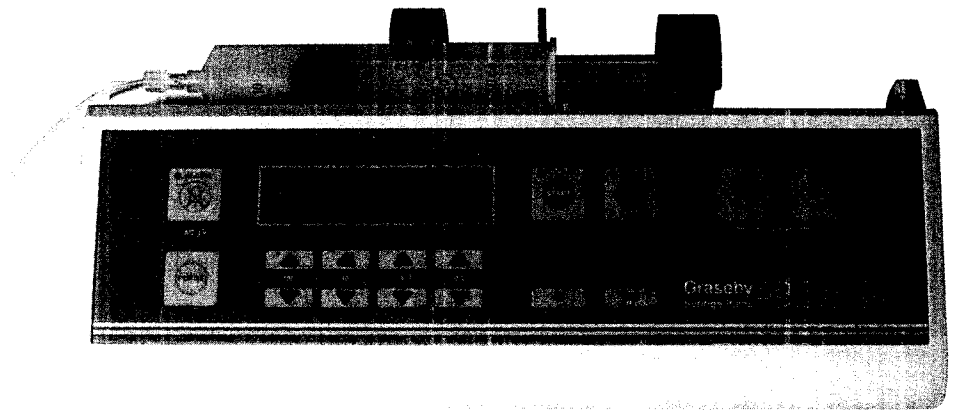
Graseby 3100 Syringe Pump

Instruction Manual



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SIMS GRASEBY

ADDENDUM TO 3000 SYRINGE PUMPS

Introduction

If the 9-pin RS232 connector that is situated on the rear of the 3150, 3200, 3300, 3400 and 3500 syringe pump's is utilised then the following **WARNING** must be observed.

WARNING

When the pump is carrying out an infusion only items of equipment that conform to EN60950 may be connected to the 9-pin RS232 connector that is situated at the rear of the 3150, 3200, 3300, 3400 and 3500 pumps. Otherwise, the safety of the patient may be compromised.

Introduction

The following **WARNINGS** must be observed if a syringe size smaller than 50/60 ml is going to be used for an infusion.

WARNING

When using a syringe smaller than 50/60 ml on a 3200 pump the occlusion pressure will increase as the diameter of the syringe decreases, i.e. the smaller the syringe the higher the pressure.

For high risk or critical infusions the use of the dedicated 3200 Extension set incorporating the pressure sensing disc is recommended in order that occlusion pressure can be appropriately set and monitored during an infusion.

WARNING

When using a syringe smaller than 50/60 ml on a 3100, 3150, 3300, 3400 or 3500 pump the occlusion pressure will increase as the diameter of the syringe decreases, i.e. the smaller the syringe the higher the pressure.

Part Number 0131-0226-A

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SIMS Graseby seeks constantly to improve their products, therefore, the specification for the 3100 pump is subject to change.

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Introduction

Thank you for choosing a Graseby 3100 Syringe Pump. This Instruction Manual contains important information on operating and looking after your pump. So that you are completely familiar with all of the pump's features please take the time to read this manual before switching the pump on.

It is important that all users of the 3100 have been trained in how to use the pump.

Warnings and cautions

Do **not** immerse the 3100 in any liquids.

Do **not** expose the 3100 to strong organic solvents.

The 3100 is **not** designed to allow it to be sterilised; any attempt at sterilisation will seriously damage the pump.

Do **not** operate the 3100 if the temperature is lower than 5°C or higher than 40°C.

The 3100 must be set to operate with the brand of syringe that is going to be used. Using a different brand to that selected could lead to the incorrect amount of drug being administered.

Users are reminded, that if a pump has been subject to a fluid spill or has been dropped, then it must be checked by a suitably qualified person before being used.

Protect the 3100 from strong magnetic and electromagnetic fields such as hospital X-ray machines and magnetic scanners.

As with all computer electronic equipment, high powered electromagnetic radiation, such as from diathermy equipment in close proximity may affect the 3100, although no hazard will be caused.

The 3100 is not suitable for use in the presence of inflammable anaesthetic mixtures that include air; oxygen or nitrous oxide.

The Graseby 3100

The Graseby 3100 Syringe Pump is a micro-computer controlled syringe pump developed by SIMS Graseby Ltd for the administration of sterile liquids. This compact, robust unit is designed to sit on a table top or to be mounted on a pole clamp. *(Part No. 0131-0129)*. It caters for 20, 30, 50 and 60ml syringes.

All the controls are clear and easy to use. The Graseby 3100 incorporates a dot matrix VFD display that provides the user with a constant indication of the pump's operation.

The Graseby 3100 Syringe Pump can be programmed by the user to work with one of a range of makes of syringe and automatically senses the syringe size. It can easily be set to dispense liquids at rates of 0.1 to 199.9ml/hr (with a 50/60ml syringe) in steps of 0.1ml.

The pump keeps a running total of the volume of liquid infused, even when the infusion is stopped and restarted (or switched off).

Safety features have been built into the pump and its software. The Graseby 3100 carries out self testing routines every time it is switched on. Users are warned of such incidents as occlusion or power failure by both visible and audible alarms.

The unit can be run from mains power, or from internal rechargeable batteries which give three to four hours of use.

Features

Designed in consultation with users, key features of the Graseby 3100 are:

- Simple to use
- Ergonomic styling
- Simple to service
- Battery or mains power
- Advanced safety features
- Caters for different makes of syringe
- Automatic syringe size sensing
- Clear text display
- Comprehensive range of alarms, including the detection of an incorrectly placed syringe.
- 3 minute near empty warning alarm
- Drip proof
- Purge facility

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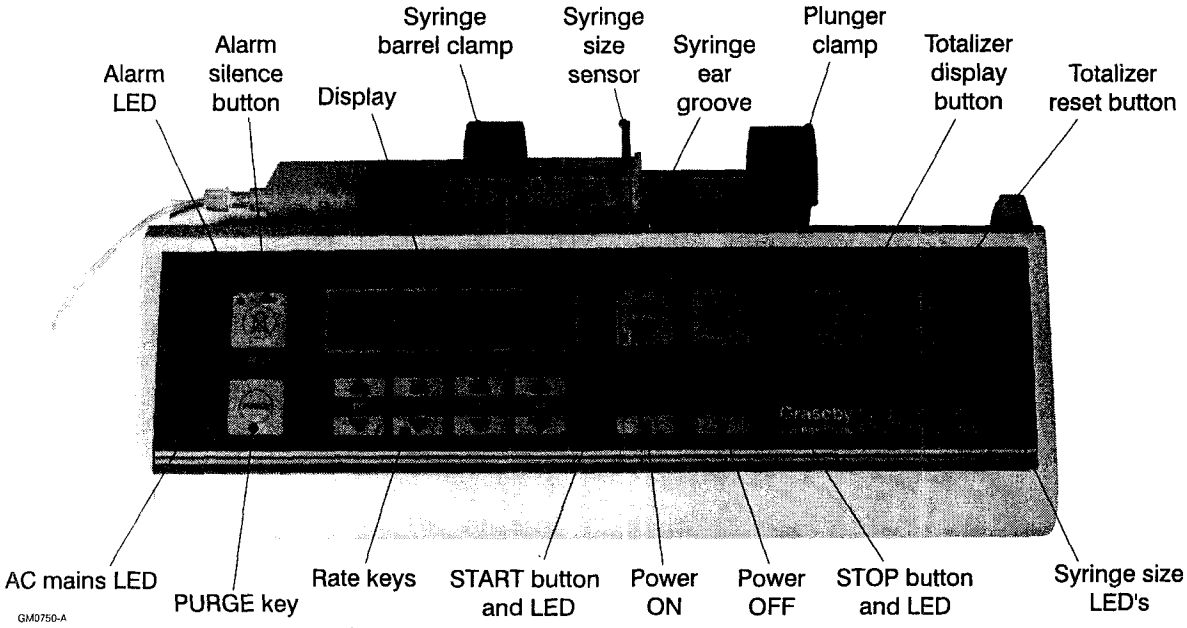


Diagram 1.

1. Switch On

Connect to AC power. For battery operation refer to section 9. Insert the AC power lead into the rear of the pump. Secure the mains lead with the clamp as shown in Diagram 2, to prevent it from being accidentally pulled out of the pump.

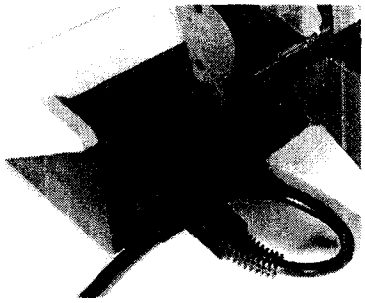


Diagram 2. The Mains Lead Clamp

Connect the pump to the AC power supply.

The AC power indicator lamp will illuminate. Press the **ON** key to switch on the pump. A brief self-test procedure will then be performed, during which a bleep will be heard. The pump is now in 'set-up' mode, ready for an infusion rate to be set. In the unlikely event of a fault being detected during the self-test procedure a continuous audible alarm will sound and a fault code will be displayed.

WARNING

If a fault is detected during the self-test procedures a continuous audible alarm will sound and a fault code number will appear on the display (see page 14).

Do not attempt to use the pump if a fault is detected. Make a note of the fault code number; switch off the pump and contact a qualified Technician or SIMS Graseby (Customer Care).

2. Load Syringe

2.1 Syringe Type

When the pump is switched on (Section 1) the display will briefly indicate which syringe make the pump is calibrated for.

WARNING

Do not proceed any further if the brand of syringe you are using is different from the brand that is displayed.

Refer to SIMS Graseby or a qualified technician. A qualified technician can re-calibrate the Graseby 3100 to accept any of the following syringe makes:

Syringe Make/Displayed Message	*Syringe Sizes Available*
BD	**20ml, 30/35ml, 50/60ml**
BRAUN OMNIFIX	"
MONOJECT	"
TERUMO	"
FRESENIUS	**(50ml only)**

2.2 Prime Syringe

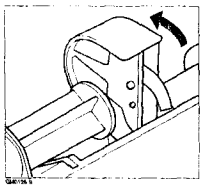
Fill and prime the syringe and catheter in the normal way, ensuring all the air is expelled.

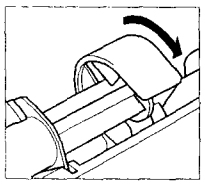
2.3 Insert Syringe

Carefully swing the syringe plunger clamp away from the body of the pump, until it clicks. Slide the syringe plunger clamp fully to the right.

Pull the syringe barrel clamp upwards and insert the primed syringe into the syringe trough. Ensure at the same time that the ear of the syringe is located in the groove and pushed fully to the left. The syringe size sensor should rest on the syringe barrel and the syringe size indicator lamp should indicate the syringe size.

> **WARNING**
>
> Check that the syringe size indicator LED confirms the syringe size. **DO NOT PROCEED ANY FURTHER** if this is different from the size of the syringe you are using. Refer to SIMS Graseby or a qualified technician.





Lower the syringe barrel clamp onto the syringe. Slide the syringe plunger clamp to the left until it is touching the plunger. Swing the clamp back until it clicks over the syringe plunger. Ensure the plunger cross piece is correctly placed within the syringe plunger clamp (see diagram).

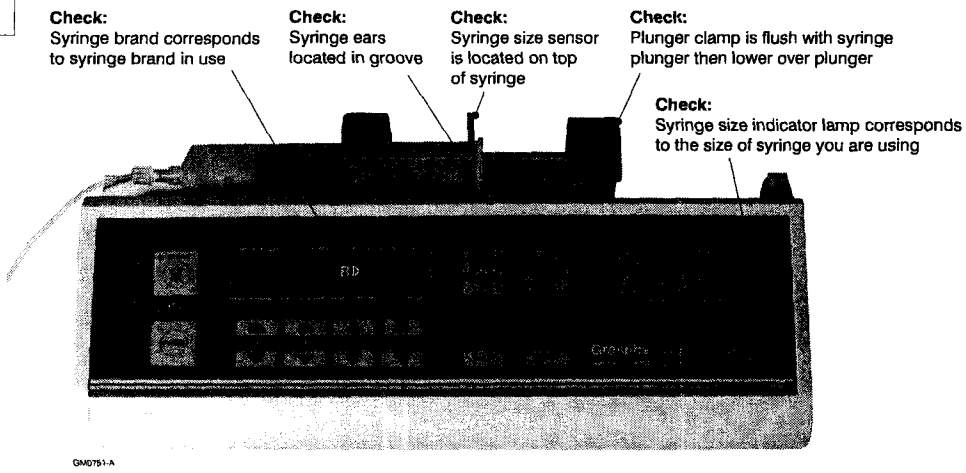

Check:
Syringe brand corresponds to syringe brand in use
Check:
Syringe ears located in groove
Check:
Syringe size sensor is located on top of syringe
Check:
Plunger clamp is flush with syringe plunger then lower over plunger
Check:
Syringe size indicator lamp corresponds to the size of syringe you are using
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Diagram. 3. Inserting the Syringe

The syringes are disposable types for single-use only

3. Set Infusion Rate

3.1 Infusion Rate Memory

After switch on, the pump will display the ml/hr infusion rate used last time the pump was run. Note: not the last rate set.

It is possible to set the pump at 0.0ml/hr. Of course the pump will not run at this rate. The rate invalid alarm will sound if the **START** button is pressed.

3.2 Setting the ml/hr Infusion Rate

If the memorised rate is not required then the rate can be altered by pressing the arrowed keys underneath the display. To facilitate ease of setting up, the buttons are arranged in pairs of up and down keys for hundreds, tens, units and tenths of the ml/hr infusion rate. The infusion rate can be set to between 0.1ml/hr to 199.9ml/hr in steps of 0.1ml/hr.

For applications where flow uniformity is a concern, rates of 1.0ml/hr or above are recommended.

3.3 Start-up Time

The time taken for a syringe pump to achieve the set infusion rate after being started is known as the start-up time.

The start-up time is dependant on the infusion rate, the higher the infusion rate the faster the start-up time.

The typical start-up times for the Graseby 3100 are (using 50/60ml BD syringes):-

at 5ml/hr = 3 minutes
at 1ml/hr =15 minutes
(independant test data)[1]

3.4 Accuracy

The volumetric accuracy of the Graseby 3100 is +or- 2%.

[1] See MDA evaluation 149 (2/1993)

4. Purging the Infusion Line (disconnect tubing from patient)

4.1

WARNING
Before removing any superfluous air from the syringe and infusion line, ensure that the infusion line is disconnected from the patient.

For safety reasons the purge facility cannot be used whilst the pump is infusing. Press the **PURGE** key, the display will show the message **"PRESS AGAIN"**. Press the **PURGE** key immediately and hold it depressed. Whilst running in the purge mode the alarm lamp and run lamp will flash and the display will show the total fluid quantity delivered since the purge button was pressed. Maximum purge volume is 2ml for all syringe sizes.

Purge speed is 199.9ml/hr (50/60ml syringes), 100ml/hr (30ml syringes) and 60ml/hr (20ml syringes).

Press **START** to begin the infusion at the set ml/hr rate. The make and the size of the syringe will be displayed briefly, followed by the infusion rate.

5. Start Infusion

5.1

During the infusion the green start lamp will flash. In addition, the **"pump running"** indicator arrows on the display will flash. If anything occurs to disrupt the infusion the pump will alarm. See Section 9; Alarms.

6. Totalizer Feature

This tells you how much drug has been infused by the 3100.

The totalizer can be accessed when the pump is running or when the pump is stopped. Press the display totalizer key. For a few seconds the display will show "TOTAL :XXX.X ML".

If you wish to reset the totalizer, press the reset totalizer key when the total is displayed. It is not possible to reset the totalizer without first accessing the display totalizer program. The totalizer can only be reset when the pump is stopped.

7. Stop Infusion

Press the **STOP** button to stop the infusion. The yellow stop lamp will illuminate and the pump running indicators in the display will disappear.

8. Switch Off

8 Switch Off

Stop the infusion (Section 7). Press the **OFF** button to switch the pump off. The pump is now in **"sleep"** mode. The AC power indicator lamp will remain illuminated if the pump is connected to AC power.

Disconnect from the AC power supply if the pump is not going to be used for any length of time; the AC power indicator lamp will then extinguish. To return to **"set-up"** mode whilst the unit is in **"sleep"** mode, press the **ON** button. To conserve battery life it is recommended to run the pump connected to the AC power supply. *Note that running the pump on AC power automatically charges the batteries.* For notes on battery operation see Section 10.

There are several alarm states, each accompanied by a descriptive message on the display, an audible alarm and a flashing red alarm light. If the pump was infusing at the time of the alarm then the pump will have stopped automatically (except for the low battery and nearly empty alarm). To silence the alarm press the button with the "cross bell" symbol. Set out below and on the following pages are the alarm messages and an explanation of their meaning.

9. Alarms

9.1 Syringe Plunger Clamp Disengaged

CLAMP OPEN

ALARM TYPE - 2 second quiet alarm.

CAUSE The syringe plunger clamp has not been correctly located over the syringe plunger.

The clamp is not correctly engaged onto the drive mechanism.

ACTION Reposition the clamp on the syringe plunger. Ensure that the syringe plunger crosspiece is correctly placed within the plunger clamp.

9.2 Syringe Invalid

SYRINGE INVALID

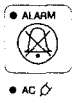
ALARM TYPE - 2 second quiet alarm.

CAUSE The syringe size sensor does not detect a syringe in the syringe trough. Syringe size is too small.

ACTION Ensure syringe size is appropriate i.e. 20ml, 30/35ml or 50/60ml.

Reposition the syringe barrel on the syringe trough.

9.3 Rate Invalid



RATE INVALID

ALARM TYPE - 2 second quiet alarm.

CAUSE The **START** button has been pressed with the infusion rate set to 00.0ml/hr.

The **START** button has been pressed with too high an infusion rate set for the syringe size in use (above 60ml/hr for a 20ml syringe, above 100ml/hr for a 30ml syringe).

ACTION Set desired infusion rate then press the **START** button.

9.4 Occlusion

OCCLUSION

ALARM TYPE - Pulsing loud alarm (silenceable)

CAUSE There is a pressure build-up on the syringe plunger clamp, probably because of a blocked infusion line. The infusion has stopped.

ACTION Silence the alarm.

> **WARNING**
> **To prevent a bolus being delivered to the patient, remove the pressure by opening the pump's plunger clamp before dealing with an occlusion.**

To do this swing the syringe plunger clamp away from the body of the pump and slide to the right. Then deal with the occlusion. Reposition the syringe plunger clamp. Press **START** to restart the infusion.

9.4.1 The Occlusion Sensing System

The Graseby 3100 has a sensitive, internal occlusion pressure detector which detects the pressure build-up on the syringe plunger clamp most often caused by a blocked infusion line. This system detects a load between 3.5 and 4.2kg. For BD 50/60ml syringes this is equivalent to about 350mmHg. Note that for other brands and sizes this will vary considerably.

The factory set occlusion pressure is about 350mmHg and the maximum operating pressure is about 600mmHg (6.68 - 11.45KPa).

9.4.2 Time to alarm following occlusion

The time to alarm following occlusion is due to a number of factors which include the compliance in the syringe and infusion line and largely the infusion rate.

Independent tests show that under normal conditions, using a non compliant infusion line (eg vygon Lectrocath 100cm infusion line), the time to alarm following occlusion at 1.0ml/hr is approximately 27 minutes at the factory occlusion pressure setting of about 350mmHg. This time can be reduced by reducing the internal occlusion pressure. A lower pressure will

give a shorter time to alarm but there may be an increase in false alarms below the 250mmHg setting. For neontal use we recommend reducing this pressure to below the 250mmHg setting.

The maximum time to alarm following occlusion will occur at the lowest settable infusion rate of 0.1ml/hr. At rates as low as this the time to alarm is likely to be 10hrs.

9.5 The Nearly Empty Alarm System

The Graseby 3100 Syringe Pump has a unique intelligent Nearly Empty Alarm System.
One of two messages is displayed.

<3 mins to END

NB This alarm only operates at infusion rates at or below 100ml/hr.

ALARM TYPE - Intermittent quiet alarm.

CAUSE The syringe is nearly empty, there are less than 3 minutes before the syringe enters the **KVO** mode (Section 9.6). The pump is continuing to infuse at the set rate.

ACTION This alarm can be silenced. If you wish to continue infusing fill, prime and reload the next syringe (Section 2.2). If not, stop the infusion when the end of infusion alarm sounds (Section 9.6/9.7).

NEARLY EMPTY

NB This alarm only operates at infusion rates above 100ml/hr. **OR** when a syringe is loaded with approximately 2.5cm or less fluid remaining in the syringe.

ALARM TYPE - Intermittent quiet alarm.

CAUSE The syringe is nearly empty. The pump is continuing to infuse at the set rate.

ACTION This alarm can be silenced. If you wish to continue infusing fill, prime and reload the next syringe (Section 2.2). If not, stop the infusion when the **SYRINGE EMPTY** alarm sounds (Section 9.7).

9.6 Infusion Ended (KVO mode)

END (KVO = .5)

NB This alarm only operates at infusion rates at or below 100ml/hr.

ALARM TYPE - Pulsing loud alarm (silenceable)

CAUSE The infusion has stopped. The pump is running at a rate of 0.5ml/hr or less, if set rate is less, to keep the vein open.

ACTION Press the alarm silence key to silence the audible alarm. If you wish to continue the infusion fill, prime and reload the next syringe (Section 2.2). **You may infuse the small amount of drug left in the syringe at the set infusion rate by stopping and re-starting the pump.** If you do not wish to continue infusing press the **STOP** button to end the infusion.

9.7 Empty/Occlusion

EMPTY/OCCLUSION

ALARM TYPE - Pulsing loud alarm (silenceable)

CAUSE The syringe is empty and the infusion is complete. The pump has stopped infusing or an occlusion has occured within the nearly empty zone (e.g. the last 13ml of a 50/60ml BD syringe).

ACTION Press the alarm silence key to silence the audible alarm.Prepare, prime and load a new syringe or switch off the pump.

9.8 Not Infusing

NOT INFUSING

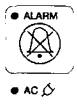
ALARM TYPE - Intermittent quiet alarm (silenceable)

CAUSE The pump has been switched on but the **START** button has not been pressed.

CAUSE The infusion may have been stopped (or completed) and the user has neglected to press the **START** button again (or switch the pump off).

ACTION Press **START** to commence infusion or switch pump off.

9.9 AC Power Failure



AC MAINS FAIL

ALARM TYPE - Intermittent quiet alarm (silenceable)

CAUSE AC power supply has been interrupted. The pump will continue to run on its internal batteries. A fully charged pump will operate for more than 3 hours.

ACTION This alarm can be silenced to continue running the pump on batteries. Reconnect to AC power if possible.

9.10 On Battery

ON BATTERY

ALARM TYPE - No audible alarm, screen indication only. A 'B' will be shown adjacent to the right pump running indicator arrow.

CAUSE The pump is operating on its internal batteries.

ACTION Reconnect to AC power supply if desired.

9.11 Low Battery

LOW BATTERY

ALARM TYPE - Intermittent quiet alarm (not silenceable)

CAUSE The pump is operating on its internal batteries, but it may not be possible for the infusion to continue much longer.

ACTION Reconnect to AC power supply **immediately**.

9.12 Fault Mode

*** FAULT 46 ***

ALARM TYPE - Continuous loud alarm (not silenceable)

CAUSE There is a fault with the pump.

ACTION

WARNING
Do not use the pump if a FAULT code occurs

Make a note of the fault code number.

Switch the pump off and contact SIMS Graseby or a qualified Technician.

The SIMS Graseby Technical Service Manual (part number 00SM-0131) gives further information on the pump's fault codes.

10. Battery Operation

When the pump is switched on but not connected to the AC power supply it will (if the batteries are charged) operate as described, except that:

— The AC power lamp will remain unlit.

— The following message will be displayed:

ON BATTERY

— A 'B' will be shown adjacent to the right pump running indicator arrow.
— The low battery alarm is operative (Section 9.11).
— The batteries will be fully charged if the pump has been connected to mains power for more than 14 hours.
— When fully charged, the batteries will power the pump for more than 3 hours.

11. Positioning the pump for use

The pump should be positioned and operated horizontally. It may be placed on a flat stable surface or mounted on a vertical IV pole or rail using the pole clamp.

Pole clamp part number 0131-0129.

12. Care of the Graseby 3100 Syringe Pump

12.1 Cleaning

The pump may be decontaminated by wiping it with a mild disinfectant solution.

For example, the disinfectant solution may be made by using sodium hypochlorite diluted with water, to give a solution of 0.1% avaliable chlorine. The chlorine concentration will be stated on the product label. The solution must be freshly made and used within 24 hours of preparation.

WARNING
Do not immerse the pump in water

12.2 Maintenance

The Department of Health, in its publication MDA DB 9503, has recommended that infusion pumps are checked by a qualified technician at regular intervals.

SIMS Graseby Ltd supports this policy, and recommends that, for all our products, the functional and safety tests listed in the Technical Manuals are carried out annually.

Additionally, with reference to the Department of Health publication 'SAB(94)26 July 1994', we recommend that any of our products that have been dropped, or subjected to severe fluid spills, should be removed from use immediately, and be checked by a qualified technician.

12.3 Technical service manual

For technical and repair information refer to the Graseby Technical Service Manual, part number 00SM-0131.

12.4 Spare parts

For further infomation contact:
SIMS Graseby (Customer Care) or your local distributor.

A list of Spare parts and accessories is provided in each of the following:

- The Graseby 3000 Series Recommended Spares and Price List, part number TPF-00002.
- The Graseby Technical Service Manual, part number 00SM-0131.

13. Standards

Insulation

The pump is a Class II (double insulated) device.
(Also classified as Internally Powered Equipment.)

Type CF (Cardiac Floating) insulation on all inputs.

Safety

IEC 601 - 1.

EMC

IEC601 - 1 - 2.

Fluid ingress

IPX1 protection against drops of water falling vertically.

Patent and Registered Design applied for.

CE Marking

The **CE** mark demonstrates that the pump conforms to the requirements in the European Council Directive 93/42/EEC concerning medical devices.

The number 0473 identifies the Notified Body under which the Quality Systems operated within SIMS Graseby Ltd are assessed.

Disposal

When the time comes to dispose of the 3100 Syringe Pump or its accessories do so in the best way to minimise any negative impact on the environment.

There are three batteries inside the pump that contain harmful lead and sulphuric acid. First discharge the batteries by operating the pump, then dismantle the pump and remove all three batteries. Do not open up the batteries as this will release the acid. Do not incinerate them as they may explode. Separate them from the everyday waste, as indicated by the graphic symbol on the batteries.

You may be able to use special recycling or disposal schemes. To find out about these contact your local waste disposal service.

Separate any other parts of the equipment where arrangements can be made for their recovery, either by recycling or energy recovery. Larger plastic parts are marked with a material identification code to facilitate recycling.

Important: Existing national or local regulations concerning waste disposal must take precedence over this advice.

Specifications

Power supply:	100 to 120 V or 220 to 240 V AC.
Supply frequency:	50 to 60 Hz.
Input power:	15 VA.
Battery type:	Sealed lead acid (cyclon).
Battery life:	More than 3 hours when fully charged and under normal operating conditions.
Syringe types:	BD Plastipak 20ml, 30ml, 50/60ml Braun Omnifix 20ml, 30ml, 50/60ml Braun Perfusor 50ml (optional) Monoject 20ml, 30/35ml, 50/60ml Terumo 20ml, 30/35ml, 50/60ml Fresenius 50ml.
Flow rate:	0.1-199.9 ml/hr in 0.1ml increments.
Drive accuracy: complete	The delivery volume is accurate to within ±2% over a syringe length (excluding the start-up time)
Weight:	Not exceeding 3.5 kg including batteries and pole clamp.
Nominal Size:	325 mm x 195 mm x 115 mm (with pole clamp fitted and plunger clamp closed).
Temperature range:	Storage conditions: -40° to +70°C, 30 to 90% Rh, 700 to 1060 hPa Operating conditions: +5° to +40°C, 30 to 75% Rh, 700 to 1060 hPa
Occlusion alarm	The pump gives an occlusion alarm if the force on the syringe plunger is between 3.5 and 4.2 kg. (It is possible to adjust this force) e.g. if a BD 50/60 ml syringe is used a maximum occlusion pressure will be 550 mmHg

CAUTION
Equipment not suitable for use in the presence of inflammable anaesthetics mixture with air, with oxygen or nitrous oxide.

As with all computer electronic equipment, high powered electromagnetic radiation, such as from diathermy equipment in close proximity, can affect operation, although no hazard will be caused.